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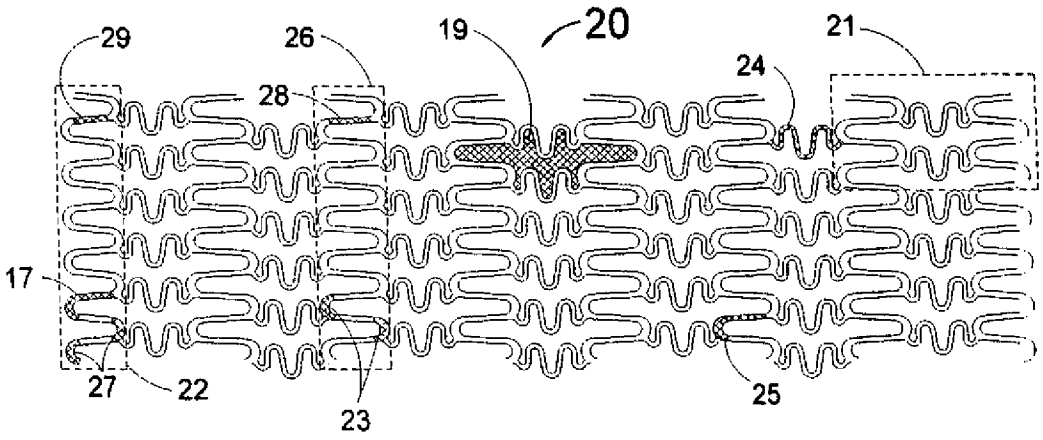
(54) Title: STENT WITH OPTIMAL STRENGTH AND RADIO-OPACITY CHARACTERISTICS



(57) Abstract: The present invention is a stent that is designed to have optimal strength and radio-opacity with good biocompatibility. To achieve optimal radio-opacity, the stent design of the present invention is adjusted to the specific radio-opacity and strength characteristics of the metal from which the stent is fabricated. What is more, coatings such as parylene may be needed to avoid corrosion from stents with less biocompatible materials and/or dissimilar metal on the stent's outer surface. The achievement of optimal radio-opacity occurs in a stent that ideally is only 0.004 inches wall thickness or less. Such a stent would have a pre-deployment outer diameter (profile) that would be at least 0.003 inches less than currently marketed stents. Ideally, the sten described herein would have a wall thickness between 0.0025 inches and 0.004 inches.

WO 02/24111 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

STENT WITH OPTIMAL STRENGTH AND RADIO-OPACITY CHARACTERISTICS

FIELD OF USE

This invention is in the field of stents for implantation into a vessel of a human body.

BACKGROUND OF THE INVENTION

Stents are well known medical devices that are used for maintaining the patency of a large variety of vessels of the human body. A more frequent use is for implantation into the coronary vasculature. Although stents have been used for this purpose for more than ten years, and some current stent designs such as the CORDIS BX Velocity ® stent, Cordis Corporation, Miami Lakes, FL, have the required flexibility and radial rigidity to provide an excellent clinical result, they are not always clearly seen under standard fluoroscopy.

Many current tubular stents use a multiplicity of circumferential sets of strut members connected by either straight longitudinal connecting links or undulating longitudinal connecting links. The circumferential sets of strut members are typically formed from a series of diagonal sections connected to curved sections forming a closed-ring, zig-zag structure. This structure opens up as the stent expands to form the element in the stent that provides structural support for the arterial wall. A single strut member can be thought of

as a diagonal section connected to a curved section within one of the circumferential sets of strut members. In current stent designs such as the BX Velocity ® stent, these sets of strut members are formed from a single piece of metal having a uniform wall thickness and generally uniform strut width. Although a stent with uniform width of the strut members will function, if the width is increased to add strength or radio-opacity, the sets of strut members will experience increased strain upon expansion. High strain can cause cracking of the metal and potential fatigue failure of the stent under the cyclic stress of a beating heart.

Existing highly radio-opaque stents, such as the gold plated NIROYAL stent sold by Boston Scientific, Inc., Natick MA, can obscure the inside of the vessel due to the high radio-opacity over the entire length of the stent. The BeStent sold by Medtronic, Inc., Minneapolis MN, has small gold markers at the ends of the stent. Those markers only mark an end point without allowing visualization of the entire end set of strut members.

Fischell et al, in US Patent No. 6,086,604, discloses a stent with the end sets of strut members being gold plated. Such a stent would have ideal radio-opacity but may be subject to the corrosive effects incurred through placement of dissimilar in an electrolytic solution such as blood. There has also been significant evidence that gold is a poor surface material for stents because it may increase the risk of subacute thrombosis or restenosis. Further, Fischell

et al, US Patent No. 5,697,971 discloses in its FIG. 7, a stainless steel stent with increased width diagonal sections in all the circumferential sets of strut members.

SUMMARY OF THE INVENTION

An ideally radio-opaque stent would have end sets of strut members that are highly radio-opaque so that they can be readily seen, even using low power fluoroscopy, and would further contain a central section that is visible but not too bright so as to obscure the lumen when high power cine film angiograms are taken. The stent should also have only one material on its outside surface to avoid potential corrosion; that material should not promote subacute thrombosis or restenosis.

The present invention is a stent that is designed to have optimal strength and radio-opacity with good biocompatibility. Unfortunately, the choices of appropriate biocompatible metals available as thin wall tubing for stent construction are somewhat limited. To achieve optimal radio-opacity, the stent design of the present invention is adjusted to the specific radio-opacity and strength characteristics of the metal from which the stent is fabricated. What is more, coatings such as parylene may be needed to avoid corrosion from stents with less biocompatible materials and/or dissimilar metals on the stent's outer surface. Of extreme importance to the present invention is the achievement of optimal radio-opacity in a stent that ideally is only 0.004 inches

wall thickness or less. Such a stent would have a pre-deployment outer diameter (profile) that would be at least 0.003 inches less than currently marketed stents. Ideally, the stent described herein would have a wall thickness between 0.0025 inches and 0.004 inches.

Described herein are the novel design elements for stents formed from the following materials:

1. A highly radio-opaque metal such as tantalum;

2. Metals somewhat more radio-opaque than stainless steel, such as the cobalt based alloy L605;

3. Stents coated or plated with highly radio-opaque materials like gold; and

4. Layered materials such as alternative layers of tantalum and stainless steel. The novel design elements that are described herein include:

1. Tapered strut width for stents formed from highly radio-opaque metals. Although reducing the width of the longitudinally diagonal section alone will reduce radio-opacity without significantly affecting radial strength, by having a taper on the curved sections of the circumferential sets of strut members, a greatly reduced level of strain upon stent expansion can be achieved without sacrificing radial strength. This is extremely important, as it

allows a stent to be made much stronger than a stent with uniform width of the strut members while staying within the same strain limit for the material.

Tantalum is a metal that used in stents, which is highly radio-opaque. The optimal radio-opacity for a stent design using tantalum could have uniform width for the circumferential sets of strut members and a wall thickness of about 0.0025 inches. To provide more radial strength and to reduce the probability of the stent ends flaring out during deployment, a wall thickness of about 0.003 inches to 0.035 inches would be highly desirable. With uniform width sets of strut members, a 0.035 inches wall thickness tantalum stent would be too bright under cine angiography. To reduce the radio-opacity of the design without significantly impacting the radial strength of the deployed stent, the present invention envisions curved sections and diagonal sections, either or both of which could have a variable or tapered width. The curved sections should be tapered (wider at the center compared to the ends) to reduce strain as previously described. The longitudinally diagonal sections can be thinner in the center than at the ends, to reduce radio-opacity for the central sets of strut members.

It is envisioned that the novel stent described herein might have wider diagonal sections for the end sets of strut members as compared to the central sets of strut members. This feature would enhance the radio-opacity of the end sets of strut members while retaining a moderate level of radio-opacity for the

central sets of strut members. It is also envisioned to have both reduced width diagonals and/or reduced wall thickness for the central sets of strut members. It should be remembered that it is fluoroscopic visualization of the end sets of strut members that is most important for visualizing stents placed inside a coronary artery.)

2. Thicker diagonal sections for metals with radio-opacity slightly better than stainless steel. The cobalt/tungsten alloy L605 is a stronger and more radio-opaque metal compared to stainless steel. To achieve optimal radio-opacity using L605 with uniform width sets of strut members, the wall thickness is optimally equal to or greater than 0.0045 inches. To provide optimal radio-opacity with such a metal in stents of wall thickness 0.004 inches or less, the present invention envisions wider diagonal sections in the sets of strut members. Thus, the tapered diagonal sections would be wider than the curved sections. The tapered curved section design for reduced strain may also be highly desirable for stents made from the L605 alloy.

3. End sets of strut members with thinner curved sections. Stent deliverability into curved coronary arteries is improved when the longitudinally diagonal sections of the end sets of strut members have a decreased length as compared to the length of the diagonal sections of the central sets of strut members. A shorter length of the diagonal sections will also reduce outward

flaring upon expansion of the stent. Decreasing end flaring of the deployed stent is of particular importance for stents having very thin walls.

Previous designs that describe a stent with shorter diagonal sections in the end sets of strut members are limited by the strain limit allowed for the end sets of strut members. As a result, if the end sets of strut members are made as strong as possible while being limited by the maximum allowable strain for that metal, the central sets of strut members will not have optimized radial strength. The present invention envisions optimizing the radial strength for all sets of strut members, i.e., the metal in all sets of strut members just reach the maximum allowable strain at the limiting diameter for the stent's expansion. To achieve this desired attribute, the stent described herein has the curved sections of the end sets of strut members being less wide than the curved sections of the central sets of strut members.

1. Good side branch arterial access while maintaining small cell size. The stents described herein are typically closed cell stents, having a curved section of a central set of strut members connected to an adjacent set of strut members by a longitudinally extending link. In one embodiment of the present invention, the circumferential sets of strut members are joined by undulating longitudinal connecting links with each link having a multiplicity of curved segments so as to increase the perimeter of the stent's closed cells. One aspect of the present invention is that the perimeter of each of the stent's

closed cells should be at least 9 mm long. This design parameter allows each cell of the stent to be expanded to a circular diameter of approximately 3 mm (i.e., 9/? mm ~ 3 mm). This feature allows the "unjailing" of side branches of the artery into which the stent is placed. The ideal design to be radially strong, prevent plaque prolapse and still allow sidebranch access will have a maximum deployed cell area of less than 0.005 in.^{2} while having a cell perimeter that is at least 9 mm in length, so as to allow unjailing of side branches. A good cell for side branch access should have a perimeter length between 9 mm and 11 mm. (i.e. an expandable circular diameter between 2.86 mm and 3.5 mm). Cell perimeters between 9.5 and 10 mm are optimal.

5. Flexible undulating longitudinal links with good support between adjacent sets of strut members. To provide a strong bridge connection between adjacent circumferential sets of strut members, the flexible undulating longitudinal connecting links should have nearly equal extension in the circumferential direction on each side of a line drawn between the attachment points of the flexible undulating longitudinal connecting link to the curved sections of adjacent sets of strut members. "N" and inverted "N" shapes for the connecting links inherently have equal circumferential displacement on each side of the line connecting their attachment points. The specially designed "M" or "W" shapes of the present invention also provide this desirable attribute. Nearly equal circumferential lengths on either side of a line drawn between the attachment points of the flexible undulating longitudinal connecting links help in

preventing plaque from pushing the "M" or "W" shaped link inward when the stent is deployed into an artery.

The "M" and "W" shapes are of particular advantage in obtaining the desired attribute of small area cells that have good side branch access capability because of an increased perimeter length. It should also be understood that the "M" and "W" shapes each add an additional half cycle of undulating link length to the cell perimeter as compared to an "N" shaped link design, thus improving the stent's longitudinal flexibility. It should also be noted that a "W" link is simply an inverted "M" link.

1. Variable thickness radio-opaque coatings. The NIROYAL ™ stent has a uniform thickness of gold plating, which makes the center too radio-opaque as compared to the radio-opacity of the end sets of strut members. Fischell et al., US Patent No. 6,086,604, teaches stents having gold placed at the end sets of strut members. This creates a potential for corrosion from dissimilar metals, namely, gold and stainless steel. The present invention envisions a gold coating that is sufficiently thick on the end sets of strut members to provide optimal radio-opacity with a thin coating of gold on the rest of the stent. This design prevents obscuring of the arterial lumen while providing an exterior surface for the stent that is a single metal, thus avoiding electrolytic corrosion.

7. Polymer coatings for stents coated with gold or having dissimilar metal surfaces. For stents with non-biocompatible or dissimilar metals, the present invention envisions the use of a polymer such as parylene to coat the entire outer surface of the stent. This would improve biocompatibility and also allow attachment of organic compounds such as heparin or phosphorylcholine for reduced thrombogenicity or drugs, such as taxol or rapamycin, for reduced cell proliferation and a decreased rate of restenosis. It is also known that highly radio-opaque materials like tungsten can be mixed into polymers. A stent coating including a plastic with mixed in radio-opaque metal could be used to enhance both radio-opacity and biocompatibility. Such a polymer coating could also be advantageous with a gold coated stent.

8. Providing a variable wall thickness. The present invention also envisions next generation manufacturing techniques using photo-etching, whereby a stent pattern is etched into a thin-walled metal tube. These techniques already can produce variations in wall thickness as well as strut width for any stent pattern. The present invention envisions use of these techniques to create stents with optimal radio-opacity. In particular for a stent formed from a single metal or alloy, thicker metal at each end of the stent could increase radio-opacity there as compared to the central section of the stent. Perhaps more important is the use of multi-thickness etching techniques with a two- or three- layered tube where one of the layers is a highly radio-opaque material such as tantalum. For example, a two-layer tube having one layer of

stainless steel and a second layer of tantalum could be etched to provide the end sets of strut members with 0.001 inches of tantalum and 0.0025 inches of stainless steel while the remainder of the stent would have less than 0.0005 inches of tantalum with a stainless steel layer of 0.003 inches. It is also envisioned that there could be tantalum only on the end sets of strut members. Thus, one could produce a stent with enhanced radio-opacity at the ends with the stent having a uniform wall thickness.

One could even have a stent with increased wall thickness of a metal at the central region of the stent but still having a decreased radio-opacity at that central region if, for example, the stent had tantalum end struts with stainless steel center struts. Such a stent would be strongest in the center where the thickest plaque must be restrained.

It is also envisioned that any of the above optimal radio-opacity stent designs may be used with plastic coatings such as parylene, antithrombogenic coatings such as heparin or phosphorylcholine, or anti-proliferative coatings such as taxol or rapamycin.

Thus it is an object of the present invention to have a stent with tapered curved sections, the center of the curved sections being wider than ends of the curved sections so as to reduce plastic strain as the stent is expanded as compared to a curved section with uniform width.

Another object of the present invention is to have a stent with tapered diagonal sections in the sets of strut members where the center of the diagonal section is narrower than the ends to reduce the radio-opacity of central sets of strut members of the stent as compared to a stent with diagonal sections having a uniform width.

Still another object of the invention is to have a stent with decreased wall thickness at the central struts compared to the end struts so as to have a comparatively higher radio-opacity for the end sets of strut members.

Still another object of the present invention is to have a stent with tapered diagonal sections for one or more of the sets of strut members where the center of the diagonal section is wider than the ends to increase the radio-opacity of the end sets of strut members as compared to a stent with uniform width of the diagonal sections.

Still another object of the present invention is to have end sets of strut members having both shorter diagonal sections and thinner width curved sections as compared to those sections in the central sets of strut members.

Still another object of the present invention is to have a tantalum stent with wall thickness less than 0.035 inches having tapered sets of strut members whereby the diagonal sections are less wide than the width at the center of the curved sections.

Still another object of the present invention is to have a closed cell stent design with maximum post-deployment cell area less than 0.005 square inches and a cell perimeter length that is equal to or greater than 9 mm.

Still another object of the present invention is to have a stent with a radio-opaque metal coating where the radio-opaque metal coating has greater wall thickness on the end sets of strut members as compared to thickness on the sets of strut members at the center of the stent.

Still another object of the present invention is to have a stent etched from a multi-layer metal tube having one layer significantly more radio-opaque than at least one other layer; the etched stent being formed with increased wall thickness of the more radio-opaque layer on the end sets of strut members as compared with the sets of strut members at the center of the stent.

Still another object of the present invention is to have a closed cell stent design with "M" or "W" shaped flexible undulating longitudinal connecting links wherein the circumferential extent of the flexible undulating longitudinal connecting links is approximately equal on each side of a line drawn between the proximal and distal attachment points of the flexible undulating longitudinal connecting link.

Still another object of the present invention is to have the stent with optimized radio-opacity formed with an outer surface that is plastic coated to improve biocompatibility.

Still another object of the present invention is to have the stent with optimized radio-opacity that is coated with a plastic material and an additional organic compound to prevent thrombus formation and/or restenosis.

Still another object of the present invention is to have a stent coated with a plastic material that includes a radio-opaque filler material.

These and other objects and advantages of this invention will become apparent to the person of ordinary skill in this art field upon reading of the detailed description of this invention including the associated drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a flat layout of a prior art stent having uniform strut width for the circumferential sets of strut members.

FIG. 2 is a flat layout of a prior art stent design having "M" and "W" flexible connecting links.

FIG. 3 is an enlargement of the "M" link of the stent design of FIG. 2.

FIG. 4 is an enlargement of the improved "M" link design of the present invention.

FIG. 5 is a flat layout of the present invention stent design for a highly radio-opaque metal.

FIG. 6 is a flat layout of part of the present invention stent design of FIG. 5.

FIG. 7 is a flat layout of an alternate embodiment of part of the present invention stent design of FIG. 5.

FIG. 8 is a flat layout of the present invention stent design for a somewhat radio-opaque metal.

FIG. 9 is a flat layout of the present invention stent design for a stent coated with a radio-opaque metal.

FIG. 10 is a flat layout of an alternate embodiment of the present invention stent including an "N" shaped flexible connecting link.

FIG. 11 is a flat layout of the present invention stent design as photo-etched from a tube.

FIG. 12A is an enlargement of a section of the photo-etched stent of FIG. 11.

FIG. 12B is a longitudinal cross section at 12-12 of the enlarged section of FIG. 11 shown in FIG. 12A, the stent having a radio-opaque coating that is thickest on the end sets of strut members.

FIG. 12C is a longitudinal cross section at 12-12 of the enlarged section of FIG. 11 shown in FIG. 12A, as etched from a two-layer tube where one of the tube layers is a moderately radio-opaque metal and the other layer is a highly radio-opaque metal.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a flat layout of an embodiment of a prior art stent described by Fischell et al in US Patent Application S/N 09/192,101, incorporated herein by reference. The stent 5 of FIG. 1 is shown in its crimped, pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. The stent 5 comprises end sets of strut members 2 located at each end of the stent 5 and three central sets of strut members 6 connected each to the other by sets of longitudinally

extending undulating "N" links 4. The end sets of strut members 2 consist of alternating curved sections 7 and diagonal sections 9. The central sets of strut members 6 located longitudinally between the end sets of strut members 2 consist of alternating curved sections 3 and diagonal sections 8. In the prior art stent 5, the longitudinally diagonal sections 9 of the end sets of strut members 2 are shorter in length than the longitudinally diagonal sections 8 of the central sets of strut members 6. The shorter diagonal sections 9 will reduce the stiff longitudinal length of metal at the ends of the stent 5 to improve deliverability (by reducing "fish-scaling") and will also increase the post-expansion strength of the end sets of strut members 2 as compared with the central sets of strut members 6. In this prior art stent, the width of the curved sections 3 and 7 and the diagonal sections 8 and 9 are all the same. There is no variation in width within any set of strut members or between the end sets of strut members 2 and the central sets of strut members 6. The stent 5 is a design well suited to stainless steel having a wall thickness of 0.0045" or greater, such as found in the CORDIS BX Velocity ® stent.

If the stent 5 were formed from a highly radio-opaque metal such as tantalum with wall thickness of 0.0030 to 0.0035 inches and with sets of strut members 6 having widths of greater than the 0.005 inches that is necessary for good radial strength, then the stent would be too radio-opaque. In addition, with a wall thickness of 0.003 inches or less, the end sets of strut members 2 might have a tendency to flare outwardly into the vessel wall upon expansion.

If the end sets of strut members 2 are designed to be as strong as possible while not exceeding metal strain limits at the largest usable diameter of the stent 5, then the central sets of strut members 6 with longer diagonal sections 8 will not have maximized radial strength assuming the same strut width for both central sets of strut members 6 and end sets of strut members 2. Optimized strength at the longitudinal center of a stent is important as it is that region that must typically hold back a larger amount of plaque than at the ends of the stent.

One embodiment of the present invention provides that each set of strut members should have maximized radial strength rather than having the central sets of strut members 6 being less strong than the end sets of strut members as previously described. This design would be similar to the stent 5 of FIG. 1 with the novel improvement being that the width of the curved sections 3 of the central sets of strut members 6 would be greater than the width of the curved sections 7 of the end sets of strut members 2. The greater width of the curved sections 3 will increase the strength of the central sets of strut members 6 compensating for loss of radial strength because of the longer diagonal sections 8.

The stent 60 shown in FIG. 2 is a flat layout of a prior art stent design having "N", "M" and "W" flexible connecting links. The stent 60 is shown in its crimped pre-deployed state as it would appear if it were cut longitudinally and

then laid out into a flat, 2-dimensional configuration. It should be clearly understood that the stent 60 is in fact cylindrical in shape, which cylindrical shape would be obtained by rolling the flat configuration of FIG. 2 into a cylinder with the top points "G" joined to the bottom points "H". The stent 60 is typically fabricated by laser machining of a cylindrical, stainless steel tube.

A central set of strut members 62 is a cylindrical, closed, ring-like section of the stent 60 consisting of a multiplicity of curved sections 63 connected to diagonal sections 68. Every curved section 63 of each central set of strut members 62 is attached to a connecting link which is either a flexible "N" link 44, "M" link 64 or a "W" link 84. The stent 60 also has two end sets of strut members 72 consisting of a multiplicity of curved sections 73 connected to diagonal sections 78. In this embodiment, half of the curved sections 73 of the end set of strut members 72 are attached to "N" links 44 with the other half of the curved sections 73 situated at the extreme ends of the stent 60. The diagonal sections 78 of the end sets of strut members 72 are shorter than the diagonal sections 68 of the central sets of strut members 62. Shorter diagonal sections enhance the post-expansion radial strength of the end sets of strut members 72 as compared to the central sets of strut members 62.

FIG. 3 is an enlargement of the "M" link 64 of the prior art stent of FIG. 2. One disadvantage of this design relates to the circumferential extent of the

"M" link 64 with respect to a line 65 that could be drawn between the two attachment points 68 where the "M" link 64 attaches to the curved sections 63. Because almost all of the "M" link 64 lies above the line 65, pressure on the top of the "M" link 64 from plaque in an artery could bend the top of the "M" link 64 inward into the arterial lumen. This would be highly undesirable. Ideally, an "M" or "W" link should have an equal circumferential extent on either side of a line drawn between the attachment points to adjacent sets of strut members as shown in FIG. 4.

One aspect of the present invention is an improved "M" link 14 as shown in FIG. 4. The "M" link 14 has a circumferential extent (i.e., length) L' above and L" below the line 15. The line 15 is drawn between the attachment points 18 where the "M" link 14 attaches to adjacent curved sections 13. Such a balanced design would diminish any likelihood of the flexible connecting link 14 from expanding into the arterial lumen.

FIG. 5 is a flat layout view of a stent 20 that includes some embodiments of the present invention. The design of FIG. 5 is particularly applicable to stents made from a highly radio-opaque metal such as tantalum. The stent 20 of FIG. 5 is shown in flat, layout view based on its pre-deployed state, as it would appear before it is crimped onto a balloon catheter. The stent 20 comprises end sets of strut members 22 located at each end of the stent 20 and central sets of strut members 26 connected each to the other by sets of

individual flexible "M" links 24. The "M" links 24 are similar to the "M" link14 of FIG. 4. The end sets of strut members 22 consist of a multiplicity of curved sections 27 connected to diagonal sections 29. The central sets of strut members 26 located longitudinally between the end sets of strut members 22 consist of a multiplicity of curved sections 23 connected to diagonal sections 28.

One can also define a strut element 25 as being composed of one adjacent curved section 23 joined to a diagonal section 28. As seen in FIG. 5, it is clear that one can describe a central set of strut members 26 as being a closed, circumferential, ring-like structure comprising a multiplicity of connected strut elements 25. An end set of strut members could be likewise defined as being a multiplicity of connected strut elements 17.

The stent 20 is a closed cell stent having cells 19 formed from portions of adjacent sets of strut members connected by "M" links 24. For coronary arteries, prolapse of plaque into the arterial lumen will be minimized if the area within the cell 19 does not exceed 0.005 square inches at all diameters up to the maximum deployment diameter of the stent 20. An important aspect of stent design is to be able to place a guidewire through the expanded cell 19, into a side branch vessel. A balloon angioplasty catheter can then be advanced over the guidewire and inflated to enlarge and circularize the opening of the cell 19 to "unjail" the side branch vessel. By "unjailing" is meant

removing metal from the ostium of the side branch vessel, thus improving blood flow to that side branch. One concept of the present invention is that the cell 19 has an interior length of the perimeter that is at least 9 mm. Since balloon dilatation of the cell 19 would cause it to be near circular, a perimeter length of the cell 19 would provide a diameter of 9/?, which is approximately 3 mm. A good cell design for side branch access should have a perimeter between 9 mm and 11 mm. (i.e., an expanded circular diameter between 2.86 and 3.5 mm) where cell perimeters between 9.5 and 10 mm are optimal and would be suitable for essentially any side branch of a coronary artery.

In the stent 20, the diagonal sections 29 of the end sets of strut members 22 are shorter in length than the diagonal sections 28 of the central sets of strut members 26. The shorter diagonal sections 29 will reduce the longitudinal extent of the metal strut at the end of the stent to improve deliverability into a vessel of the human body by decreasing fish-scaling. In the stent 20, the width of the curved sections 23 and 27 and the diagonal sections 28 and 29 are different as compared to the prior art stents 5 and 6 of FIGURES 1 and 2.

The exact design of the stent 20 is most clearly seen in the expanded view of the stent section 21 of FIG. 5 as shown enlarged in FIG. 6. FIG. 6 shows that the curved sections 23 (of the central sets of strut members 26 of FIG. 5) have a width at the center of the curve W_c. The width of the curved

sections 23 taper down as one moves away from the center of the curve until a minimum width W_d is reached at the center of the section 28. To achieve this taper, the inside arc of the curved section 23 has a center that is longitudinally displaced from the center of the outside arc. This tapered shape for the curved section 23 provides a significant reduction in metal strain with little effect on the radial strength of the expanded stent as compared to a stent having sets of strut members with a uniform strut width.

This reduced strain design has several advantages. First, it can allow the present invention design to have a much greater usable range of radial expansion as compared to a stent with a uniform strut width. Second, it can allow the width at the center of the curve to be increased which increases radial strength without greatly increasing the metal strain (i.e. one can make a stronger stent). Finally, the taper reduces the amount of metal in the stent and that should improve the stent thrombogenicity.

FIG. 6 also shows a unique design for the end sets of strut members 22. The diagonal sections of the end sets of strut members 22 have a length L_{end} that is shorter than the length L of the diagonal sections 28 of the central sets of strut members 26. To maximize the radial strength of a stent along its entire length, each set of strut members should just reach the maximum allowable plastic strain for the metal being used at the largest allowable expanded diameter of the stent. In the stent of FIG. 1, the curved sections 7 of the end

sets of strut members 2 and the curved sections 3 of the central sets of strut members 6 have the same widths. As a result, the end sets of strut members 2 (which have shorter diagonal sections 9) will reach the maximum allowable diameter at a level of strain that is greater than the level of strain experienced by the central sets of strut members 6.

An optimum strength stent design would have the same strain at the maximum stent diameter for both the end sets of strut members 2 and the central sets of strut members 6. For the stent design of FIGS. 5 and 6, one desires to have the end sets of strut members 22 reach the maximum strain limit at the same stent diameter as the central sets of strut members 26. The present invention teaches a design with the width at the center of the curve W_{c_end} of the curved section 27 being less than the width W_c of the curved sections 23 of the central sets of strut members 26. This reduced width for the curved sections 23 compensates for the shorter length L_{end} of the end diagonal sections 29 so that there is the same strain in both the central and end sets of strut members 22 and 26 respectively as the stent 20 is expanded to its maximum allowable diameter.

The end sets of strut members 22 can also be tapered like the central sets of strut members 26 where the width of the strut tapers down as one moves away from the center of the curve of the curved sections 27 until a minimum width W_{d_end} is reached at the diagonal section 29. The curved

sections 23, 27 each have an inside (concave) arc and an outside (convex) arc. Each arc has a center that is longitudinally displaced from the other center.

The tapered strut design shown in FIGS. 5 and 6 also has an advantage for stents made from highly radio-opaque metals such as tantalum. If one uses uniform strut width as seen with the stent 5 of FIG. 1, then a properly designed thin-walled (0.0025 inches to 0.035 inches) wall tantalum stent may be too radio-opaque. The reduced metal from the thinner diagonal sections 28 and 29 will decrease the radio-opacity without affecting radial strength. Nominal dimensions and dimension ranges (all in inches) for a tantalum stent produced using the design of FIG. 5 are as follows:

Element	Nominal	Range
W_c	0.006	0.0045 to 0.007
W_d	0.0045	0.035 to 0.005
$W_{c\ end}$	0.0045	0.004 to 0.005
$W_{d\ end}$	0.0045	0.035 to 0.005
L	0.028	0.020 to 0.030
L_{end}	0.025	0.015 to 0.026
Wall Thickness	0.003	0.0025 to 0.035

Although the present invention shows the "M" shaped flexible link 24 being used, the present invention strut designs will function with any link shape including "N", "W", "S" "U", "V" and inverted "N", "U" and "V" designs. It should also be noted that the "M" link 24 shown in FIG. 6 has exactly five longitudinally extending curved segments 24A, 24B, 24C, 24D and 24E.

FIG. 7 is an alternative embodiment 21' of section 21 shown in FIG. 6 of the present invention stent 20 of FIG. 5. In this embodiment, the only difference is the shape of the diagonal sections 28'. The diagonal sections 28 of FIG. 6 have uniform thickness. The diagonal sections 28' of FIG. 7 are tapered from a width W_d" at the end of the diagonal section 28' where it connects to the curved sections 23' to a width W_d' at the center of the diagonal section 28'. The advantage of the inward taper of the diagonal sections 28' is that removal of more metal will reduce the radio-opacity of the longitudinal center region of the stent 20 as compared to a stent with uniform width diagonal sections 28 as seen in FIG. 6. The additional taper may also further reduce the metal strain as the stent is expanded. Although one could taper the diagonal sections 29 of the end sets of strut members 22 of FIG. 5, there is an advantage in having the end sets of strut members 22 being more radio-opaque than the central sets of strut members 26. This is because visualization of the stent ends is the most important aspect of radio-opacity for a stent. Therefore, a preferred embodiment of the present invention is as seen in FIG. 7 to have tapered diagonal sections 28' in the central sets of strut members 26 and uniform thickness diagonal sections 29 (having a greater average width) for the end sets of strut members 22.

Instead of connecting every curved section with a flexible link, an alternate embodiment may use straight links connecting only half of the curved

sections of the sets of strut members. Such a design, would also have the advantages of the reduce strain strut designs as shown in FIGS. 5, 6 and 7.

For the stent of FIG. 5, it should also be understood that the wall thickness of the central set of strut members 26 could be thinner that the wall thickness of the end set of strut members 22. Also it should be noted that the "M" links 24 also have a much narrower width as compared to the width of any strut member of the end set of strut members. Both these attributes of the stent 20 create the following desirable radio-opacity characteristics: highly radio-opaque end sets of strut members and decreased radio-opacity at the central region of the stent 20.

FIG. 8 is a flat layout view of another embodiment of the present invention showing a stent 30 made from a moderately radio-opaque metal such as the cobalt-tungsten alloy L605. The alloy L605 has great radial strength and is approximately 20% to 30% more radio-opaque than stainless steel. Therefore, with L605, the same level of radio-opacity is achieved with a stent wall thickness that is 20% to 30% less than a stent made from stainless steel. One goal in the use of L605 would be to reduce the wall thickness by 30% but end up with a stent that is still more radio-opaque than an equivalent stainless steel stent such as the stent 5 shown in FIG. 1.

The stent 30 of FIG. 8 is shown in a layout view based on its pre-deployed state, as it would appear before it is crimped onto a balloon catheter. The stent 30 comprises end sets of strut members 32 located at each end of the stent 30 and central sets of strut members 36 connected each to the other by sets of flexible "M" links 34. The "M" links 34 are similar to the "M" links 14 of FIG. 4. Each end set of strut members 32 comprises alternating curved sections 37 and diagonal sections 39 connected together to form a closed circumferential structure. The central sets of strut members 36 located longitudinally between the end sets of strut members 32 comprises curved sections 33 and diagonal sections 38 connected together to form a closed circumferential ring-like structure.

In the stent 30, the diagonal sections 39 of the end sets of strut members 32 are shorter in length than the diagonal sections 38 of the central sets of strut members 36. The shorter diagonal sections 39 will reduce the longitudinal length of metal at the end of the stent to improve deliverability into a vessel of the human body. In the stent 30, the widths of the diagonal sections 38 and 39 are different as compared to the prior art stents 5 and 60 of FIGS. 1 and 2.

The novel concepts of the stent of FIG. 8 are shown most clearly in the expanded view of the stent section 31 shown in FIG. 9. In FIG. 9 it can be seen that the diagonal sections 38 of the central sets of strut members 36 have

a width at the center T_c and a width at the end T_e where the width in the center T_c is larger than the width at the end T_e. This allows for increased radio-opacity without affecting the design of curved sections 33 that are the primary stent elements involved for stent expansion. The curved sections 33 and 37 shown in FIG. 9 are tapered similar to the curved sections 23 and 27 of FIG. 6. It is also envisioned that the curved sections 33 and 37 could have uniform width similar to the curved sections 3 and 7 of FIG. 1. The diagonal sections 39 of the end sets of strut members 32 also have a tapered shape. The diagonal sections 37 have a width in the center T_{c_end} and a width at the end T_{e_end} where the width in the center T_{c_end} is larger than the width at the end T_{e_end}. Because of the desire for the end sets of strut members 32 to be the most radio-opaque part of the stent 30, the diagonal section 39 center width T_{c_end} of the end sets of strut members 32 is shown in FIG. 9 to be wider than the width T_c of the diagonal section 38. A wider piece of metal will be more radio-opaque. Thus, the stent has curved sections with a single bend connecting the diagonal sections of its sets of strut members, and flexible connecting links connecting the curved sections of its circumferential sets of strut members.

The stent of FIG. 10 is an alternate embodiment of the present invention showing central sets of strut members 46 having curved sections 43 and diagonal sections 48 with tapered shapes similar in design to the curved sections 23' and diagonal sections 28' of the stent section 21' shown in FIG. 7. The stent 40 of FIG. 10 is shown in a layout view in its pre-deployed state as

it would appear before it is crimped onto a balloon catheter. The stent 40 comprises end sets of strut members 42 located at each end of the stent 40 and central sets of strut members 46. The sets of strut members 42 and 46 are connected each to the other by sets of individual flexible "N" links 44. The "N" links 44 are similar in shape but slightly longer than the "N" links 4 of FIG. 1. The end sets of strut members 42 consist of curved sections 47 and diagonal sections 49. The central sets of strut members 46 located longitudinally between the end sets of strut members 42 consist of curved sections 43 and diagonal sections 48.

The stent 40 is a closed cell stent having cells 45 formed from portions of adjacent sets of strut members connected by "N" links 44. Prolapse of plaque through the closed cells 45 is minimized if the expanded area of the cell 45 is less than about 0.005 $in.^2$ at any diameter up to the maximum deployment diameter of the stent 40. It is also important for an optimum stent design that a guidewire can be placed through the expanded cell 45 into a side branch vessel. A balloon angioplasty catheter would then be advanced over the guidewire, through the cell 45 and inflated to "unjail" the side branch, i.e. remove any stent strut that is blocking blood flow into that side branch. The present invention design should have an interior perimeter of the cell 45 that is at least 9 mm, thus allowing a nearly 3 mm diameter circular opening to be achieved for unjailing.

FIG. 11 is a flat layout view of another embodiment of the present invention in the form of a stent 50 that is photo-etched from a metal tube. The stent 50 is shown in its pre-deployed state as it would appear before it is crimped onto a balloon catheter. The stent 50 comprises end sets of strut members 52P and 52D located respectively at the proximal and distal ends of the stent 50. The stent 50 also has central sets of strut members 56 connected each to the other by sets of flexible "M" links 54. The "M" links 54 are similar to the "M" links 14 of FIG. 4. The end sets of strut members 52P and 52D each consists of curved sections 57 and diagonal sections 59. The central sets of strut members 56 located longitudinally between the end sets of strut members 52 consist of curved sections 53 and diagonal sections 58.

The section 55 of the photo-etched stent 50 is shown enlarged in FIG. 12A. The FIGS. 12B and 12C show two embodiments of the present invention that can provide a stent with enhanced radio-opacity at the stent ends.

FIG. 12A shows diagonal sections 58 and 59 and an "M" link 54 connecting the curved sections 53 and 57.

FIG. 12B is a longitudinal cross section at 12-12 of the stent section 55 shown in FIG. 12A. The stent design shown in FIG. 12B has a highly radio-opaque coating that is thicker on the end sets of strut members 52 as compared to the thickness on either the flex links 54 or the central sets of strut

members 56. FIG. 12B shows the coating 57C on the curved section 57 of the end set of strut members 52 being thicker than the coating 54C on the flex link 54 and also thicker than the coating 53C on the curved section 53. The most likely coating for the stent 50 would be gold plating although platinum, tantalum or any other highly radio-opaque metal could be used.

The present invention has the entire stent coated to provide an exterior surface for the stent 50 that is formed from a single metal. This reduces the potential for corrosion that can occur with dissimilar metals on the stent's exterior surface when placed in a saline solution such as the blood.

It is also envisioned that even with the entire stent coated with a highly radio-opaque metal, an additional coating of a flexible plastic such as parylene may be desirable. Such an organic coating has the additional advantage of allowing the attachment of drugs such as taxol or rapamycin to reduce restenosis. Techniques for gold plating metals such as stainless steel and controlling the thickness of the plating are well known in the art of metal plating

FIG. 12C is the longitudinal cross section at 12-12 of yet another alternate embodiment of the enlarged section 55 of FIG. 11 shown in FIG. 12A. The stent design shown in FIG. 12C is etched from a two-layer tube where one of the tube layers is a metal of conventional radio-opacity such as stainless steel and the other layer is a highly radio-opaque metal such as tantalum.

Although the total wall thickness of the stent of this embodiment remains nearly constant, the end sets of strut members 52' have a thicker layer of the radio-opaque metal than the flex links 54' or the central sets of strut members 56'. The curved section 57' of the end set of strut members 52' has conventional metal layer 57N' and radio-opaque metal layer 57R'. The flex link 54' has a standard metal layer 54N' and a radio-opaque metal layer 54R'. The central sets of strut members 56' have curved sections 53' with conventional metal layers 53N' and radio-opaque metal layers 53R'.

It can be seen from FIG. 12C that the radio-opaque metal layer 57R' of the end sets of strut members 52' is thicker than the radio-opaque metal layers 54R' and 53R'. In recent years, multi-layer photo-etching processes for metals that can control the thickness of individual layers have been developed so that the embodiment of FIG. 12C can be produced within the current state of the art of photo-etching. Using this approach, two and three layer tubing is now available from several manufacturers and can be photo-etched to make a stent with optimal high radio-opacity for the end set of strut members and reduced radio-opacity for the central sets of strut members. Specifically, a stent with the characteristics as seen in FIG. 12B or FIG. 12C would have the desirable attribute of end sets of strut members with greater radio-opacity than the remainder of the stent.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. A deployed stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical portion of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element consisting of one curved section joined at a junction point to one diagonal section with each junction point being an end point of each curved section;

a multiplicity of generally longitudinally disposed sets of flexible links with each set of flexible links connecting two of the multiplicity of circumferential sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and at least one flexible link being selected from the group that includes "M" links and "W" links; and

the sets of strut members and connecting flexible links together forming a multiplicity of closed perimeter cells, at least half of all

closed perimeter cells having an inside perimeter length greater than 9 mm.

2. The deployed stent of claim 1 wherein at least half of the closed perimeter cells having an inside area of less than 0.005 square inches at the designed limit of expansion for the stent.

3. The deployed stent of claim 2 wherein the shape of at least one of the individual flexible links is selected from a group that includes "N" shaped links and inverted "N" shaped links, each of said links having at least four generally longitudinal extending curved segments.

4. The deployed stent of claim 1 wherein at least half of the closed perimeter cells have an inside metal perimeter length that is less than 11 mm.

5. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical portion of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element

consisting of one curved section joined at a junction point to one diagonal section;

a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible segment link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved section of the multiplicity of strut elements at an attachment point situated between the center and one end of the curved section; and

the shape of at least some of the flexible links being selected from a group that includes "M" links and "W" links, wherein each of said links have at least five generally longitudinally extending curved segments, each flexible link having a proximal attachment point to a curved section of one circumferential set of strut members and a distal attachment point to a curved section of a second circumferential set of strut members, each individual flexible link having a maximum circumferential extent that is approximately the same as measured from each side of a line

drawn between the proximal attachment point and the distal attachment point of that individual flexible link.

6. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other, each set of strut members being connected to adjacent sets of strut members by longitudinal connecting links and each set of strut members forming a closed, ring-like cylindrical portion of the stent, each set of strut members consisting of a multiplicity of connected curved sections and diagonal sections, each curved section having two ends and a center situated there between, at least one set of strut members having at least half of the curved sections within the set of strut members having a tapered shape wherein the width at the center of a curved section with a tapered shape is greater than the width at the ends of a curved section with tapered shape.

7. The stent of claim 6 wherein the curved sections of one or more of the sets of strut members have inside and outside surfaces in the shape of circular arcs each circular arc having a center with the centers of the two arcs being longitudinally displaced one from the other.

8. The stent of claim 6 wherein the width at the center of the curved sections with a tapered shape is at least 0.001 inches greater than the width at the ends of the curved section with tapered shape.

9. The stent of claim 6 further comprising a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved section of the multiplicity of sets of strut elements at an attachment point situated between the center and the end of that curved section.

10. The stent of claim 6 wherein one or more of the curved sections of the sets of strut members have a tapered shape with a greater width at the center of the curved section compared to the width at the center of at least one diagonal section.

11. The stent of claim 6 wherein all curved sections have a tapered shape.

12. The stent of claim 6 wherein the sets of strut members include end sets of strut members located at each end of the stent and central sets of strut

members positioned between the end sets of strut members, the end sets of strut members having shorter diagonal sections as compared to the length of the diagonal sections of the central sets of strut members.

13. The stent of claim 12 wherein all curved sections of every central set of strut members have a tapered shape.

14. The stent of claim 12 wherein the strut width at the center of the curved sections of the end sets of strut members is less than the strut width at the center of the curved sections of the central sets of strut members.

15. The stent of claim 12 wherein the diagonal sections of the central sets of strut members have a center and two ends, at least one of the diagonal sections of the central sets of strut members has a tapered shape wherein the width of the at least one diagonal section is different at the center of the diagonal section as compared to the width at either end of that diagonal section.

16. The stent of claim 15 wherein the width of the at least one diagonal section is less at the center of that diagonal section compared to the width at either end of that diagonal section.

17. The stent of claim 15 wherein the width of the at least one diagonal section is greater at the center of that diagonal section as compared to the width at either end of that diagonal section.

18. The stent of claim 15 wherein all the diagonal sections of all of the central sets of strut members have a tapered shape.

19. The stent of claim 15 wherein all of the diagonal sections of the end sets of strut members have a tapered shape.

20. The stent of claim 6 wherein the stent is coated with a plastic material.

21. The stent of claim 20 wherein the plastic material is parylene.

22. The stent of claim 21 where a drug is attached to the plastic material.

23. The stent of claim 22 wherein the drug is from the family of drugs that include Rapamycin.

24. The stent of claim 22 wherein the drug is Taxol.

25. The stent of claim 22 wherein the drug is heparin.

26. The stent of claim 22 wherein the drug is phosphorylcholine.

27. The stent of claim 20 wherein the plastic material has a highly radio-opaque material mixed into the plastic material.

28. The stent of claim 27 wherein the radio-opaque material is tungsten.

29. The stent of claim 27 wherein the thickness of the coating is greater at the ends of the stent than in the longitudinal center of the stent.

30. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, cylindrical portion of the stent, each set of strut members comprising a multiplicity of connected curved sections and diagonal sections, the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members, the diagonal sections of the end sets of strut members having a generally greater width than the diagonal sections of the central sets of strut members so as to improve the radio-opacity of the end sets of strut

members as compared to the radio-opacity of the central sets of strut members.

31. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, cylindrical portion of the stent, each set of strut members comprising a multiplicity of connected curved sections and diagonal sections, the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members, the curved sections of the central sets of strut members having a generally greater width than the curved sections of the end sets of strut members and the diagonal sections of the central sets of strut members having a greater length as compared to the length of the diagonal sections of the end sets of strut members so as to provide approximately matched radial strength for the central sets of strut members and the end sets of strut members.

32. The stent of claim 31 wherein the width of the curved sections of the central sets of strut members is at least 0.0005 inch greater than the width of the curved sections of the end sets of strut members.

33. The stent of claim 31 wherein the length of the diagonal sections of the central sets of strut members is at least 0.001 inch greater than the length of the diagonal sections of the end sets of strut members.

34. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other and connected each to the other by one or more longitudinally extending links, each set of strut members forming a closed, cylindrical portion of the stent, each set of strut members comprising a multiplicity of connected curved sections and diagonal sections, the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members, the end sets of strut members having greater wall thickness than the central sets of strut members so as to increase the radio-opacity of the end sets of strut members.

35. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other and connected each to the

other by one or more longitudinally extending links, each set of strut members forming a closed, cylindrical portion of the stent, each set of strut members comprising a multiplicity of connected curved sections and diagonal sections, the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members, each of the sets of strut members being coated with a highly radio-opaque metal, the end sets of strut members having a greater wall thickness of the highly radio-opaque coating as compared to a lesser thickness of the radio-opaque coating on the central sets of strut members so as to have an increased radio-opacity of the end sets of strut members.

36. The stent of claim 35 wherein the highly radio-opaque metal is gold.

37. The stent of claim 35 wherein the highly radio-opaque metal is coated with a plastic material.

38. The stent of claim 37 wherein the plastic coating is parylene.

39. A stent in the form of a thin-walled, multi-cellular, tubular structure formed from tubing having two co-axial layers, a first layer and a second layer, the second layer being more radio-opaque under fluoroscopy than the first layer, the stent comprising a multiplicity of circumferential sets of

strut members, each set of strut members being longitudinally separated each from the other and connected each to the other by one or more longitudinally extending links, each set of strut members forming a closed, cylindrical portion of the stent, each set of strut members comprising a multiplicity of connected curved sections and diagonal sections, the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members, the end sets of strut members having greater wall thickness of the second layer as compared to the thickness of the second layer on the central sets of strut members thereby increasing the radio-opacity of the end sets of strut members as compared to the radio-opacity of the central sets of strut members.

40. The stent of claim 39 wherein the central sets of strut members have a greater wall thickness of the first layer as compared to the thickness of the first layer on the end sets of strut members.

41. The stent of claim 39 wherein the total wall thickness of the two layers of the end sets of strut members is approximately the same as the total wall thickness of the two layers of the central sets of strut members.

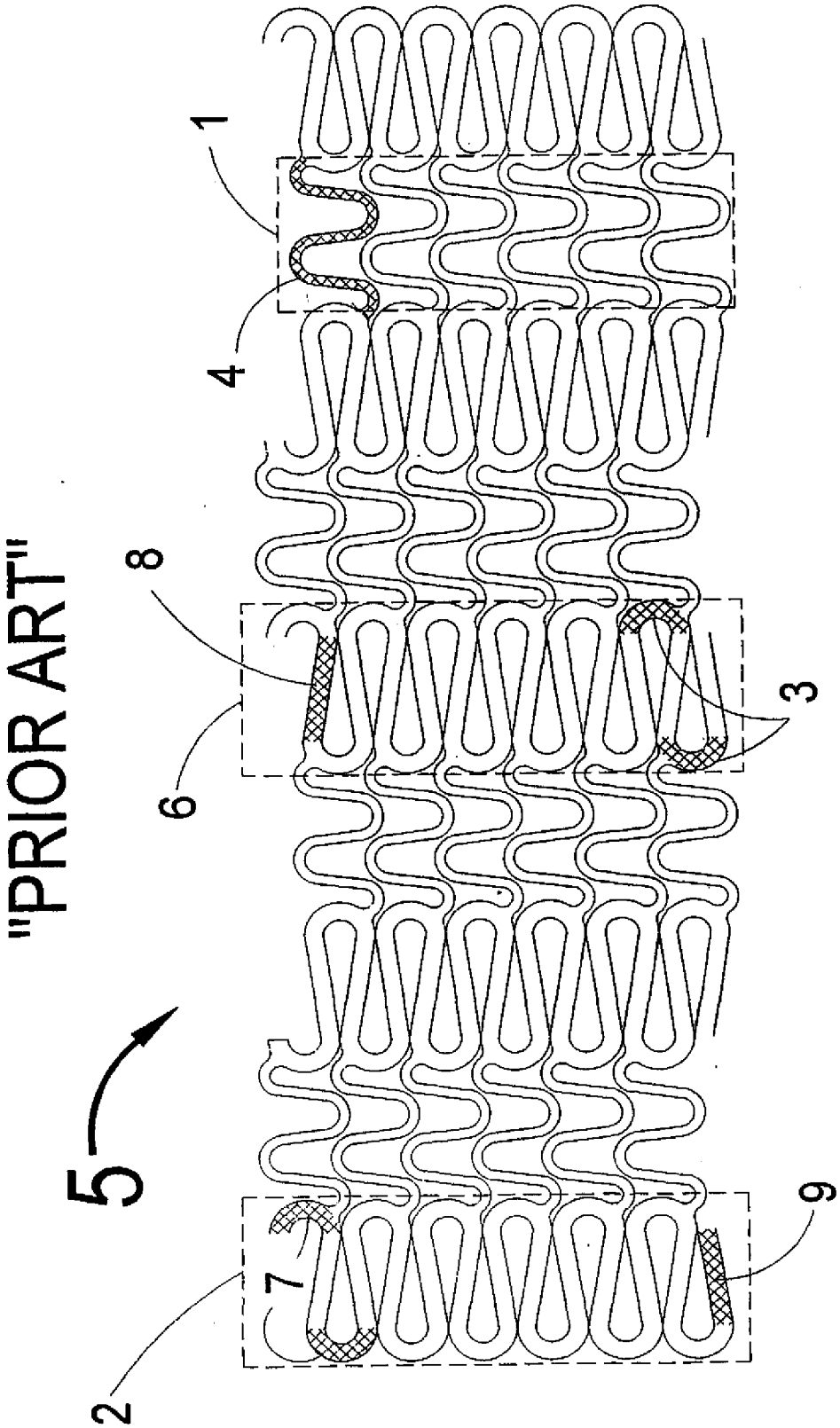


FIG. 1

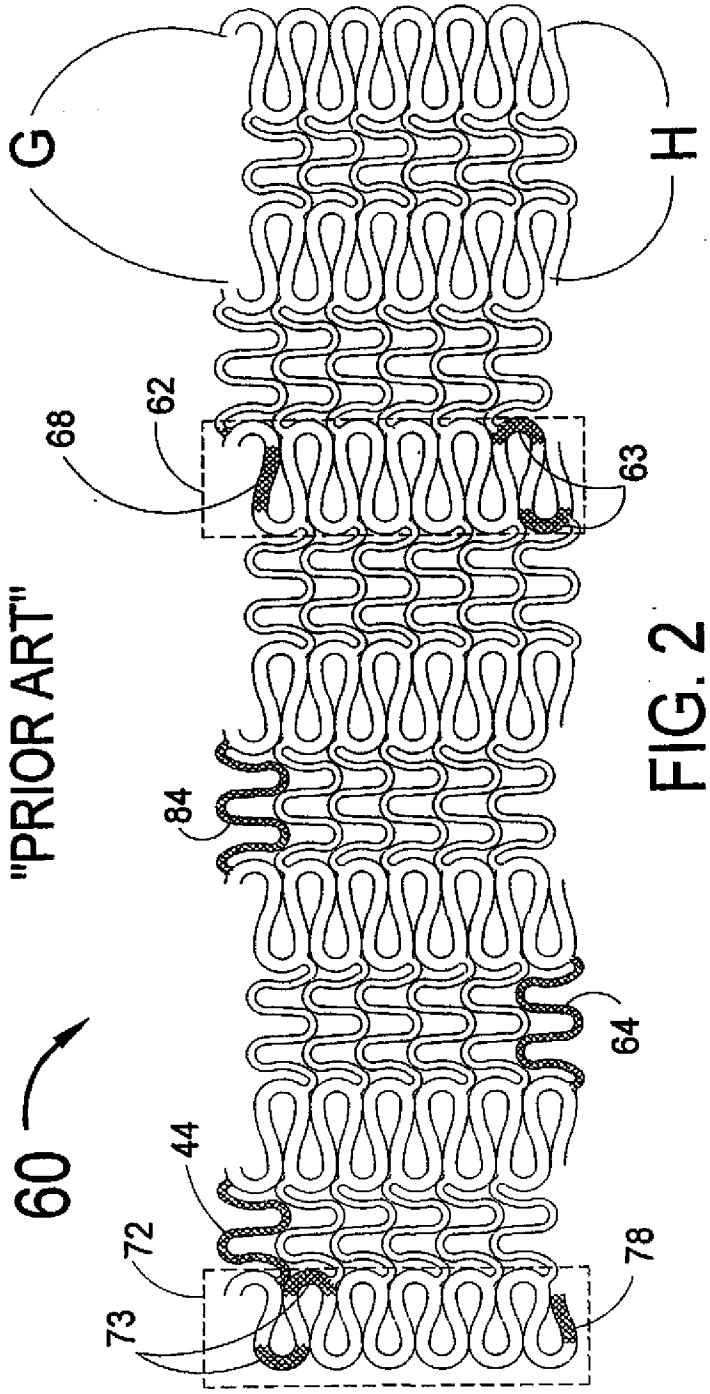


FIG. 2

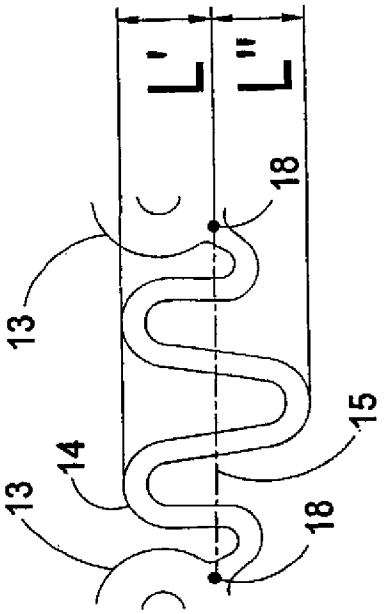


FIG. 4

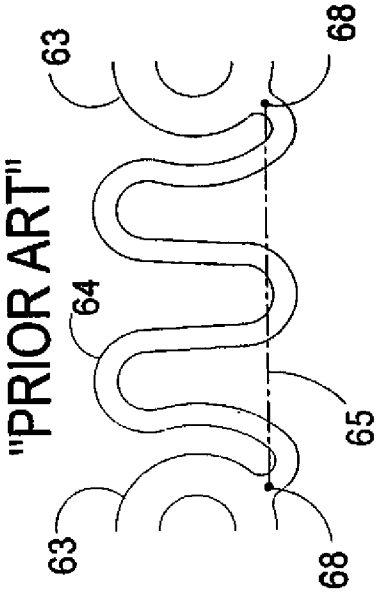


FIG. 3

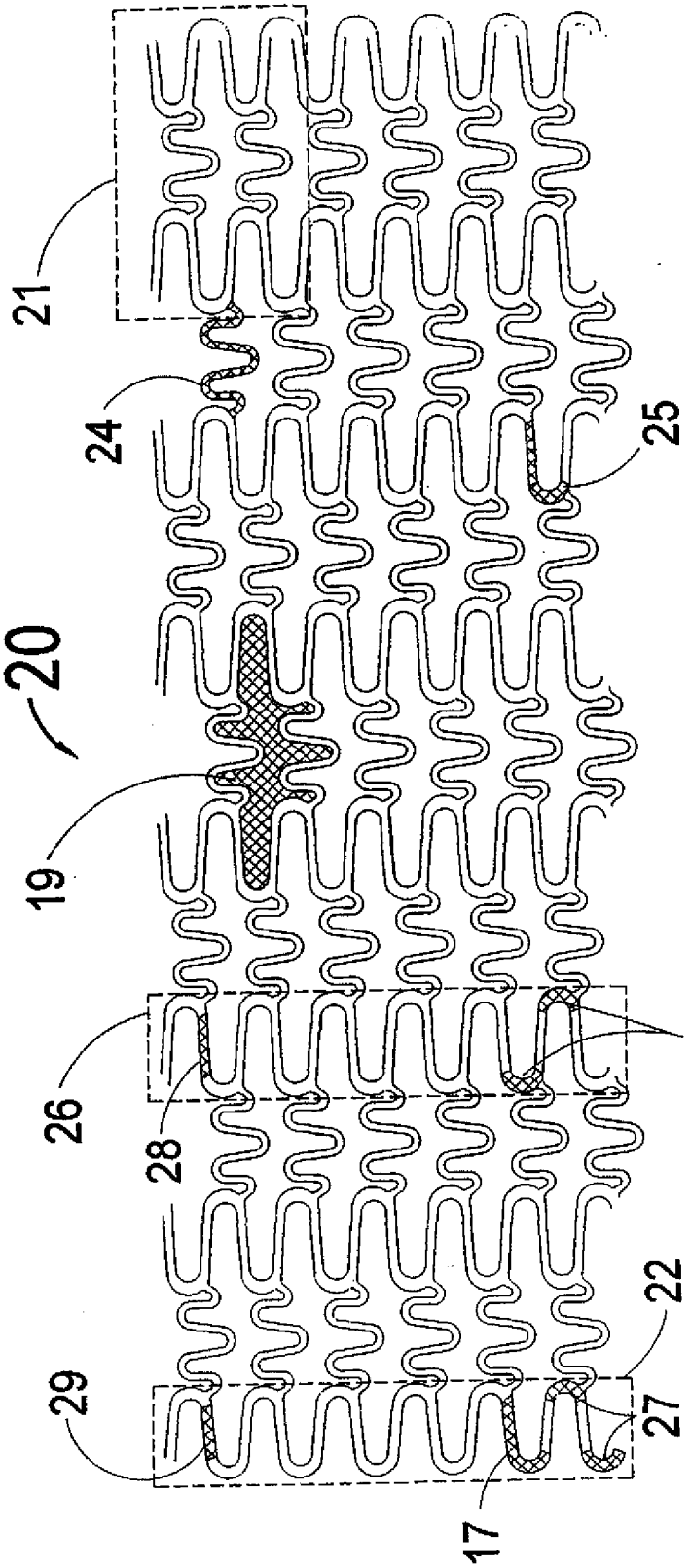


FIG. 5

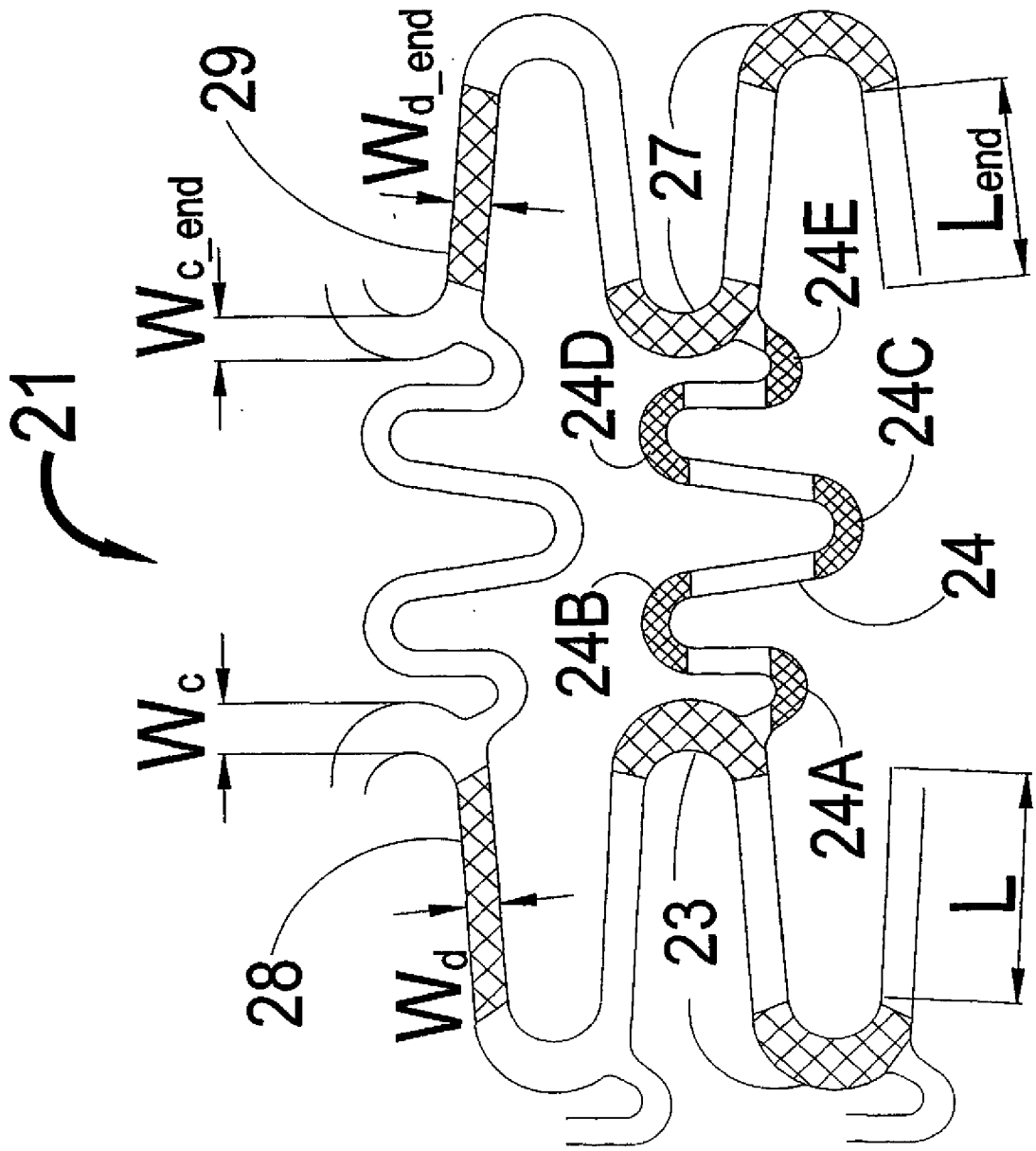


FIG. 6

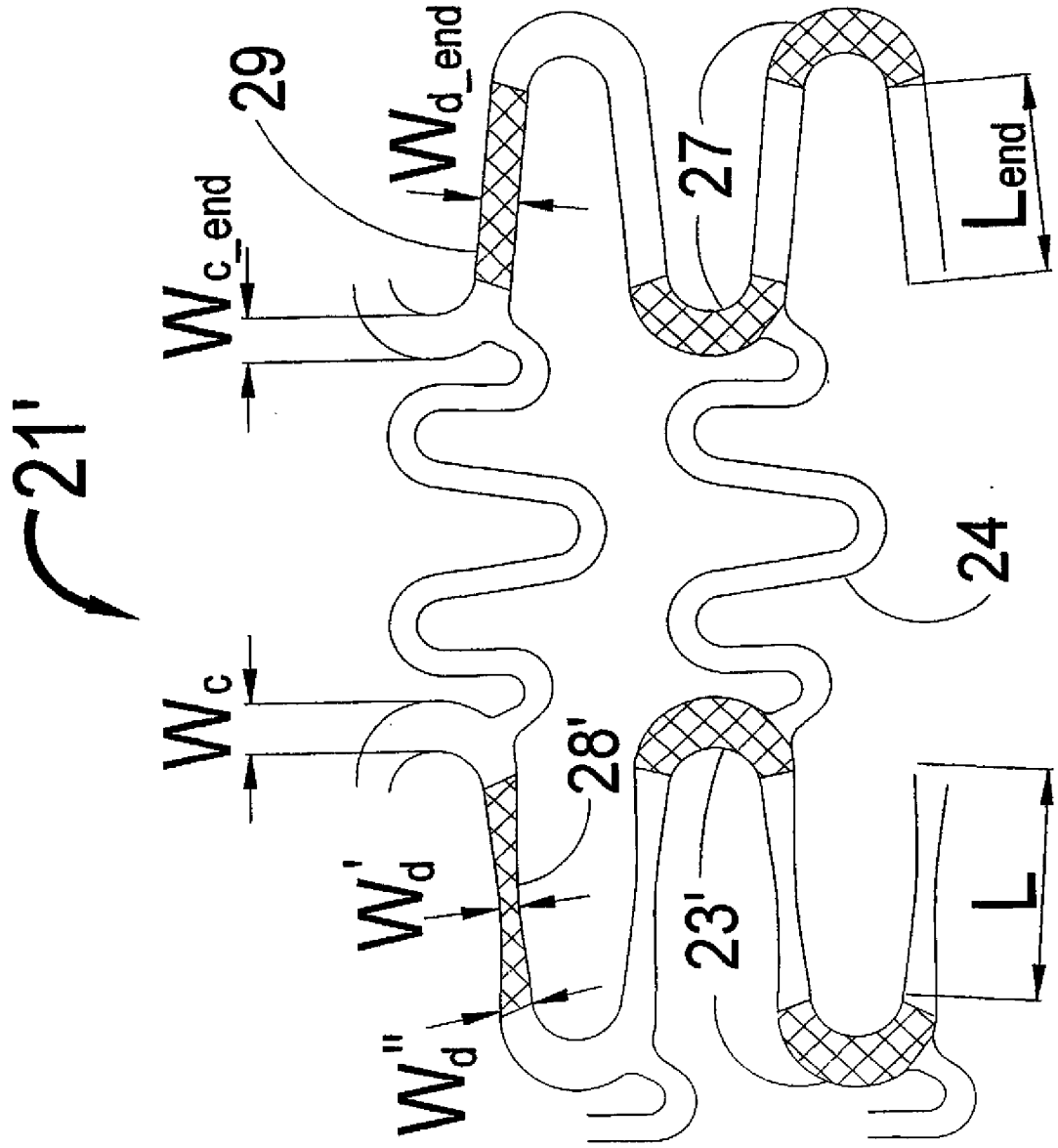


FIG. 7

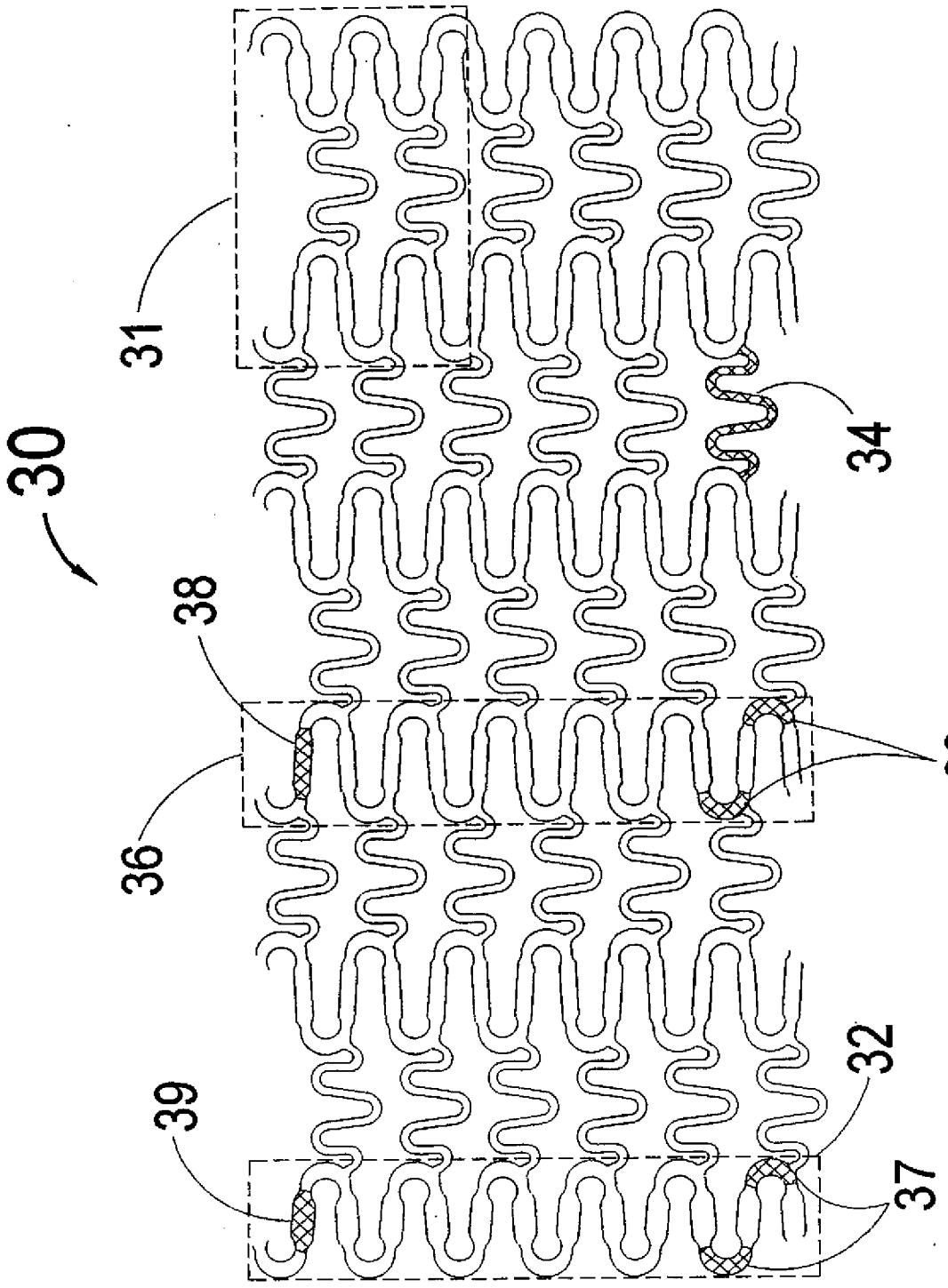


FIG. 8

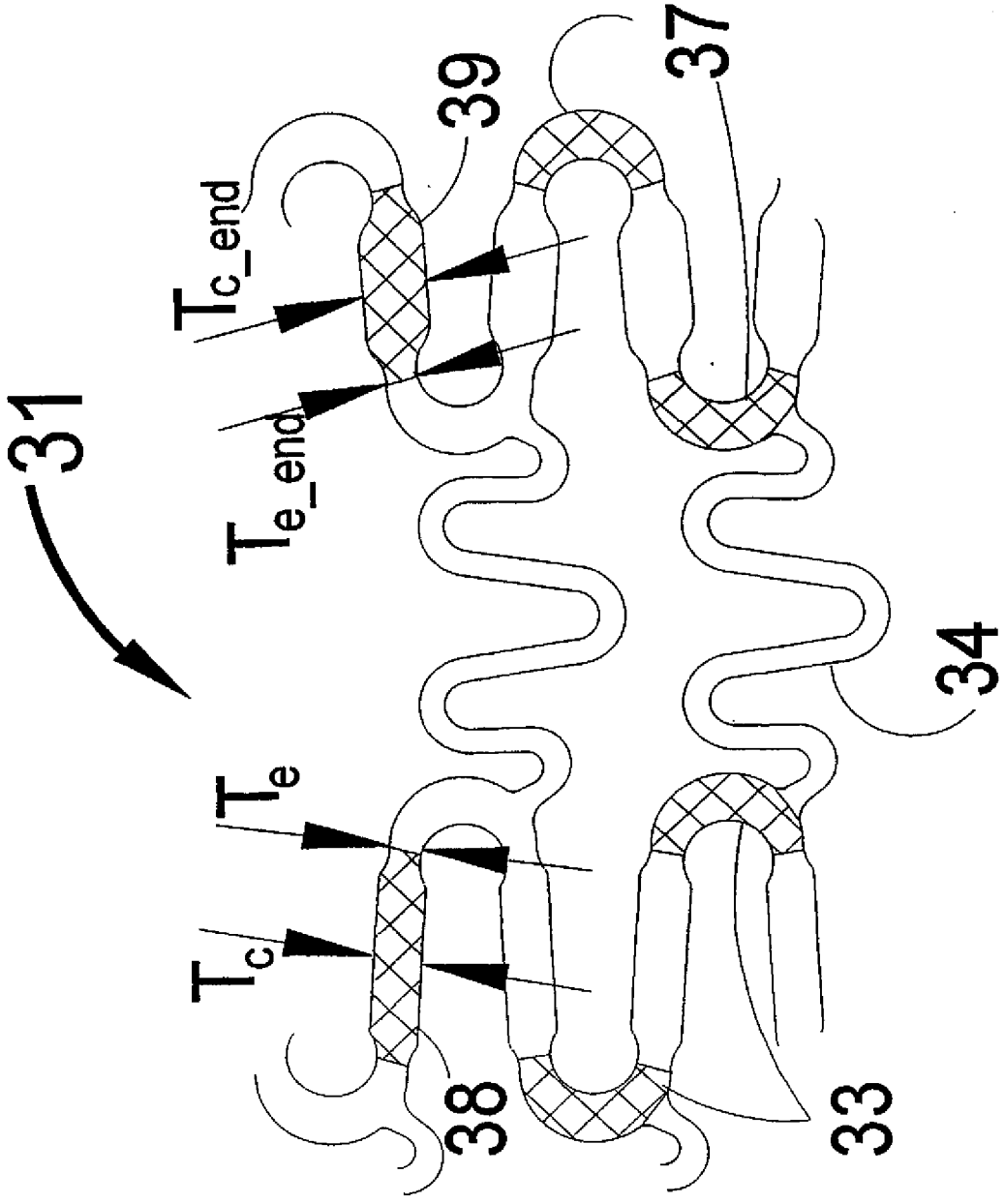


FIG. 9

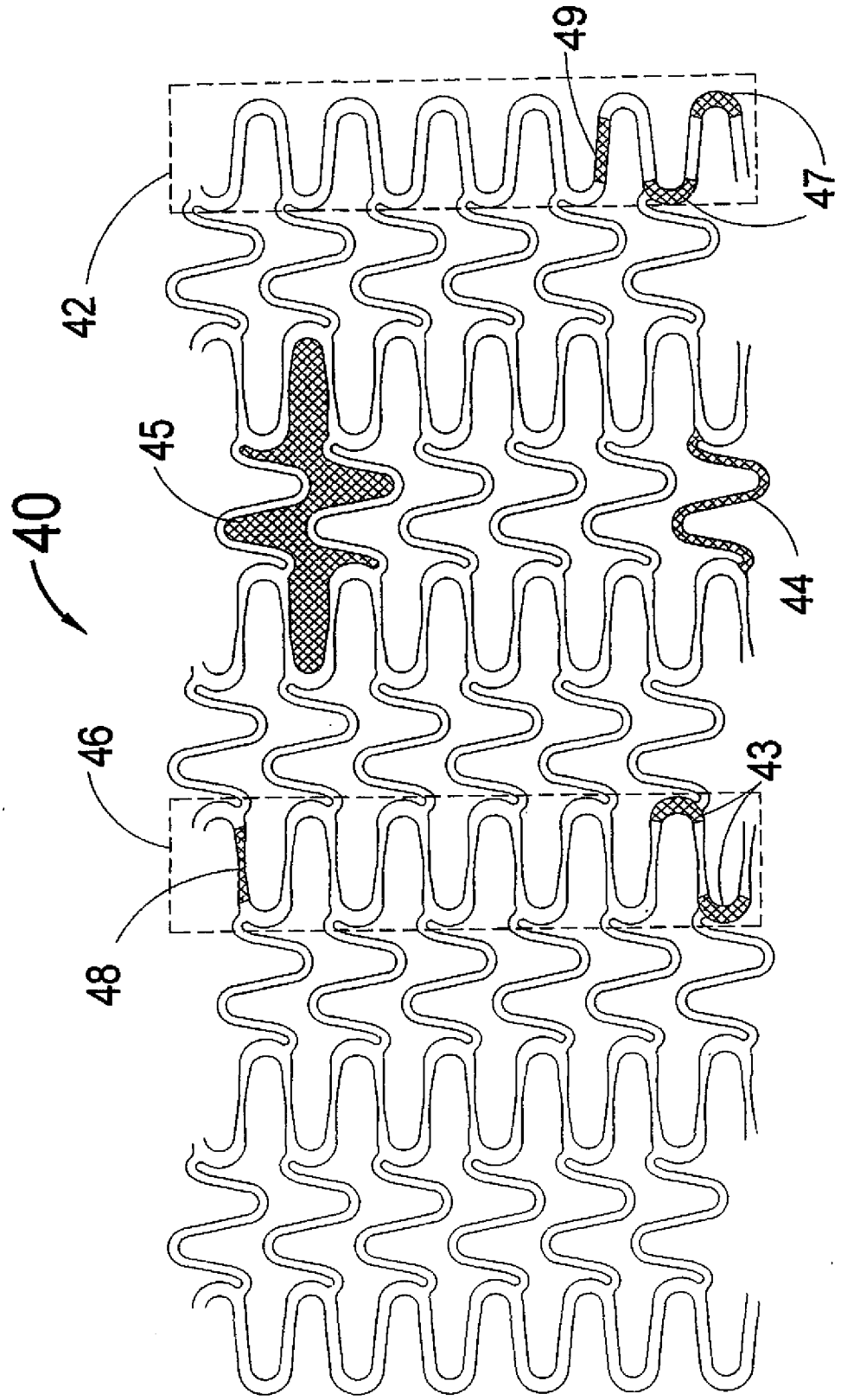


FIG. 10

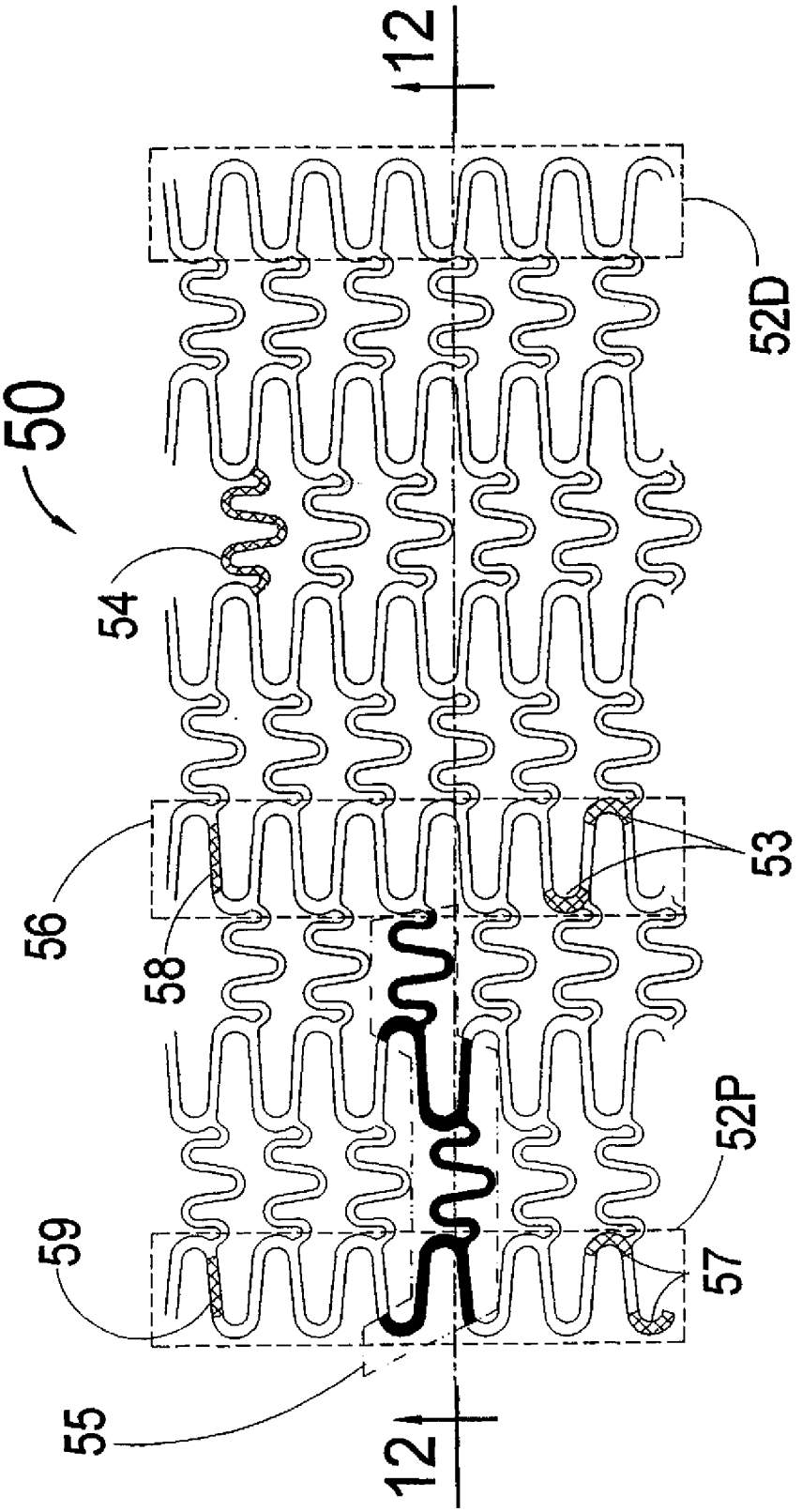


FIG. 11

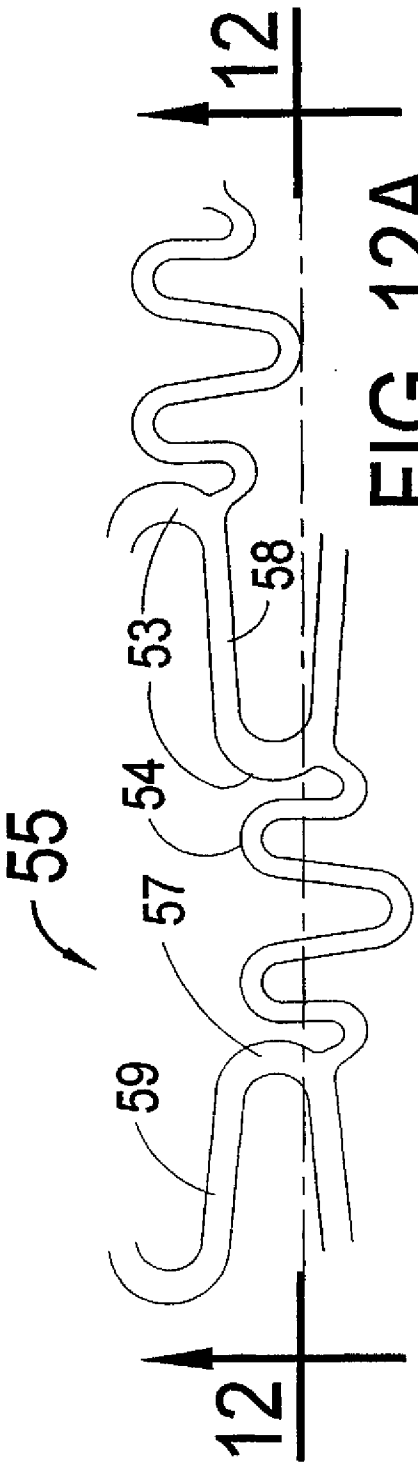


FIG. 12A

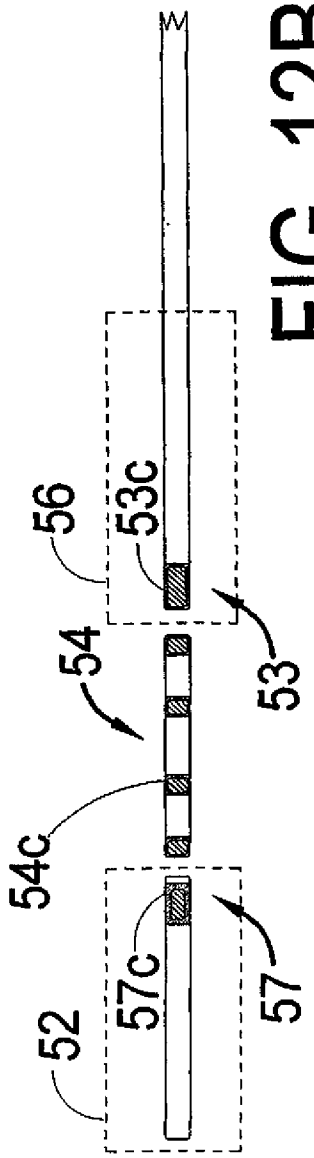


FIG. 12B

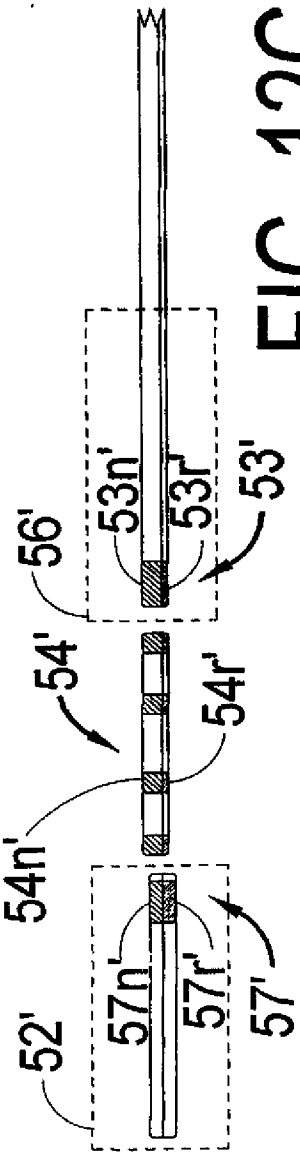


FIG. 12C

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(74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
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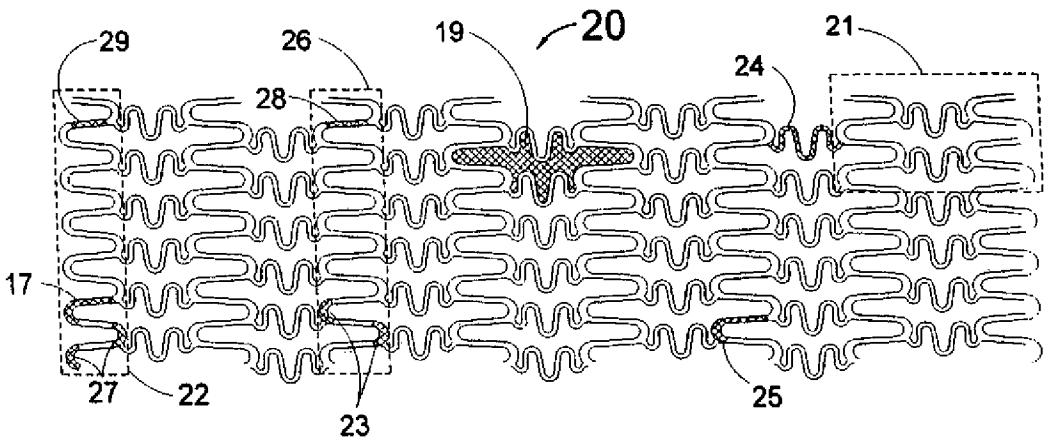
[Continued on next page]

(54) Title: STENT WITH OPTIMAL STRENGTH AND RADIO-OPACITY CHARACTERISTICS



(57) Abstract: The present invention is a stent that is designed to have optimal strength and radio-opacity with good biocompatibility. To achieve optimal radio-opacity, the stent design of the present invention is adjusted to the specific radio-opacity and strength characteristics of the metal from which the stent is fabricated. What is more, coatings such as parylene may be needed to avoid corrosion from stents with less biocompatible materials and/or dissimilar metal on the stent's outer surface. The achievement of optimal radio-opacity occurs in a stent that ideally is only 0.004 inches wall thickness or less. Such a stent would have a pre-deployment outer diameter (profile) that would be at least 0.003 inches less than currently marketed stents. Ideally, the sten described herein would have a wall thickness between 0.0025 inches and 0.004 inches.

WO 02/024111 A3

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

Inter al Application No
PCT/US 01/29082

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 916 317 A (MEDINOL LTD) 19 May 1999 (1999-05-19) paragraph '0012! - paragraph '0013! paragraph '0015! paragraph '0018! - paragraph '0020!	35,36,39
Y	---	37,38
Y	EP 0 824 900 A (ADVANCED CARDIOVASCULAR SYSTEM) 25 February 1998 (1998-02-25) column 3, line 36 - line 48 column 4, line 8 -column 7, line 11 column 7, line 42 -column 8, line 55	37,38

A	US 5 824 049 A (BATES BRIAN L ET AL) 20 October 1998 (1998-10-20) column 7, line 34 - line 58 column 10, line 39 - line 67	35-41

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 November 2002	20. 11. 2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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INTERNATIONAL SEARCH REPORT

Inten al Application No
PCT/US 01/29082

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 190 403 B1 (FISCHELL ROBERT E ET AL) 20 February 2001 (2001-02-20) column 3, line 9 -column 10, line 10	1-4
Y		5
Y	US 5 964 798 A (IMRAN MIR A) 12 October 1999 (1999-10-12) figure 1 column 1, line 40 -column 5, line 8	5
X	WO 01 00112 A (ADVANCED CARDIOVASCULAR SYSTEM) 4 January 2001 (2001-01-04) page 13, line 25 -page 27, line 23	6,8-26, 30-33
X,P	US 6 273 910 B1 (LIMON TIMOTHY A) 14 August 2001 (2001-08-14) figure 7 column 7, line 23 -column 8, line 4	30,34
X	WO 01 15632 A (ADVANCED CARDIOVASCULAR SYSTEM) 8 March 2001 (2001-03-08) page 13, line 8 -page 19, line 4	34
A	EP 1 088 528 A (SORIN BIOMEDICA CARDIO SPA) 4 April 2001 (2001-04-04) paragraph '0010! - paragraph '0031!	6,31

INTERNATIONAL SEARCH REPORT

tional application No.
PCT/US 01/29082

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 35-41

A stent comprising a multiplicity of circumferential sets of strut members connected each to the other by longitudinally extending links, each set of strut members being coated with a highly radio-opaque metal, the end sets of strut members having a greater wall thickness of coating as compared to a lesser thickness of the coating on the central sets of strut members.

2. Claims: 1-4

A stent comprising a multiplicity of circumferential sets of strut members connected each to the other by flexible links ("M" or "W" shaped), forming a multiplicity of closed perimeter cells, at least half of all closed perimeter cells having an inside perimeter length greater than 9 mm.

3. Claim : 5

A stent comprising a multiplicity of circumferential sets of strut members connected each to the other by flexible links ("M" or "W" shaped), each individual flexibal link having a maximum circunferential extent that is approximately the same as measured from each side of a line drawn between the proximal attachment point and the distal attachment point of that individual flexible link.

4. Claims: 6-33

A stent comprising a multiplicity of circumferential sets of strut members connected each to the other by longitudinally extending links, some parts of the stent (curved/diagonal, end/central parts) have greater width or length.

5. Claim : 34

A stent comprising a multiplicity of circumferential sets of strut members connected each to the other by longitudinally extending links, the end sets of strut members having a greater wall thickness than the central sets of strut members.